

REMARKS

As an initial matter, applicants expresses their gratitude to the Primary and Supervising Examiners for the courtesies extended to Applicants and Applicant's undersigned representative during the telephonic interview conducted on October 3, 2007. During that interview, proposed amendments to the claims were discussed.

The present claims incorporate the proposed amendments and the amendment suggested by the Examiner. Claim 1 is currently amended to delete the phrase "molecular recognition element," substituting the terms antibody or aptamer, support for which may be found, for example, at paragraph 43. Claim 7 has been cancelled, as this subject matter has been incorporated, in part, into Claim 1 via this amendment. Claim 1 is further amended to more specifically point out that the antibody or aptamer that specifically recognizes an altered biological agent is simply *provided*, omitting the phrase "manipulated" to clarify this step of the claim, support for which is inherent in the technology as set forth, for example, at paragraph 30. Finally claim 1 was amended to include the phrase "treatment process used to create" with respect to the finished water, at the suggestion of the Examiner, to make clear that it is the treatment process that yields the alteration to the biological agent of interest in creating the finished water. Support for this amendment may be found throughout, for example at paragraphs 17 - 21.

35 U.S.C. § 112, First Paragraph, Enablement Requirement

The Office has rejected Claims 1-12 under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement and as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In view of the instant amendments to claim 1, applicants respectfully submit that the arguments set forth by the Office are now rendered moot, in that the claims now make clear that the molecular recognition element is an antibody or aptamer. Because an antibody or aptamer may be selected using methods well known and routinely carried out in the art to which the disclosure pertains, the claims are now fully enabled for at least those reasons described below.

The Office has rejected the claim on the basis that “antibodies and nucleic acids can be efficiently used to bind to and detect various biological targets, *as long as the structures of both the binding element, i.e. antibody or nucleic acid, and the biological target are known.*” Applicants respectfully disagree with this premise. In fact, it is well known in the art that antibodies specific to an antigen may be selected with specificity *absent* specific knowledge of the particular structure serving as an antigen. (See, e.g., Current Protocols in Immunology Wiley/Greene, NY; Harlow and Lane (1989); Antibodies: A Laboratory Manual, Cold Spring Harbor Press, NY; Stites et al. (eds.) Basic and Clinical Immunology (4th ed.) Lange Medical Publications, Los Altos, Calif., and references cited therein) Aptamers may be similarly provided. In an effort to clarify the meaning of the claims, the term “manipulating” has been removed from claim 1, to more accurately convey the fact that an antibody or aptamer is selected, and does not require specific knowledge of the structure of the antibody or antigen.

The Office has also based this rejection on the lack of working examples and the likelihood of undue experimentation. However, this rejection was based on the misunderstanding that the claims required knowledge of the specific alterations of the antigen of interest, which indeed would necessitate a significant experimentation. In view of the fact that knowledge of the specific alterations is in fact not necessary, selecting a suitable antibody or aptamer is well within the ordinary skill in the art, such that working examples are not necessary to enable this aspect of the claims. Further, as stated, selecting and providing such an antibody or aptamer is well within the ordinary level of skill in the art such that only routine experimentation is required.

Thus, applicants respectfully submit that the arguments and amendments to the claims render the claims fully enabled, and as such, the rejection under 35 U.S.C. § 112, First Paragraph has been overcome and should be withdrawn.

35 U.S.C. § 112, First Paragraph, Written Description Requirement

The Office has further rejected claims 1-12 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office has cited as a basis for this rejection omission by applicants of “the type of alteration that occurs to the biological agent or how to manipulate the molecular recognition element to recognize the altered biological target.”

For reasons similar to those set forth above, this rejection is no longer applicable. In brief, the claims do not necessitate identifying the specific alteration, and selection of a specific antibody or aptamer is well within the ordinary skill in the art. As such, applicants respectfully submit that this rejection to this claim under 35 U.S.C. § 112, First Paragraph has also been overcome and should be withdrawn.

35 U.S.C. 112, Second Paragraph

The Office has additionally rejected claims 1-12 under 35 U.S.C. § 112, Second Paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In asserting this rejection, the Office argued that it was “unclear how exactly the biological agent has been ‘altered’” and that the term “manipulated” was unclear.

As set forth above, applicants have now amended the claim to clarify that an antibody or aptamer is selected according to methods well known in the art at the time of filing, and have clarified for the record that knowledge of the specific alteration is not necessary. Applicants now respectfully submit that this rejection is also rendered moot for all of the reasons set forth above.

Clarifying Amendment Suggested by the Examiner

The claims have also been amended at the suggestion of the Examiner in the telephone call received October 3, 2007. The amendment is intended to make clear that “the targeted biological agent has been altered by the treatment process used to create the finished water.” This amendment, suggested by the Examiner, has been added to clarify that the alterations to the biological agent are the result of the treatment process used to create the finished water, and finds support in the specification throughout, particularly at paragraphs 17-21. Applicants very much appreciate the Examiner’s assistance in providing this suggested amendment.

CONCLUSION

In view of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, Stephen R. Albainy-Jenei at (513) 651-6839 or salbainyjenei@fbtlaw.com.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

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